



INTENDED USE NOTICE

If you are younger than 18 do not use our Services: You should go to a doctor, preferably an ear-nose-throat doctor (an ENT) because your condition needs specialized care. Our hearing aids are intended only for users who are age 18 or older.

Our hearing aids are designed and intended for perceived mild to moderate hearing loss in adults. If you experience any of the following you may have this kind of hearing loss:

- Difficulty hearing or understanding conversations, especially in groups or noisy places, or when you can't see who is talking;
- Difficulty hearing while using a telephone;
- Fatigue due to greater listening effort;
- Needing to turn up the volume of the television, radio, or music louder than normal or loud enough for others to complain.

You can seek assistance from a hearing healthcare professional: Our devices may not be useful for more significant hearing loss or complicated hearing needs. If you cannot hear conversations in a quiet environment, or you have trouble hearing loud sounds - for example, loud music, motor vehicles, power tools, or noisy appliances - this device may not help you hear better. If you try our devices and continue to struggle with or remain concerned about your hearing, you should seek a consultation with a hearing healthcare professional.

Conditions that Require Medical Care: Prior to purchasing our devices, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma;
- Fluid, pus, or blood coming out of the ear in the past 6 months;
- Pain or discomfort in the ear;
- History of excessive ear wax or suspicion that something is in the ear canal;
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness;
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months;
- Your hearing changes; it gets worse then gets better again;
- You have worse hearing in one ear;
- You hear ringing or buzzing in only one ear.

Hearing aids should not cause pain when inserting: Remove the hearing aid device from your ear if it causes pain or discomfort when inserting or placing it in position. To try again, make sure to follow the instructions. If you feel pain or discomfort again, please contact us. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You may also report this to the FDA as an adverse event according to the instructions that appear later.

Our hearing aids are not hearing protection: You should remove the hearing aids if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove your hearing aids and use ear plugs in that environment.



The sound output should not be uncomfortable or painful: You should turn down the volume or remove the hearing aids if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your hearing aids.

You can seek medical help if a hearing piece gets stuck in your ear: If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, which could lead to serious injuries.

If you remain concerned, consult with a professional: If you try our hearing aids and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

More information, including the user instructional brochures, can be found on <https://lexiehearing.com/us/support>. You may also call (800) 499-1336 to request a paper copy of this information and other labeling.

You are advised that it is in your best health interest to consult a physician or healthcare professional before making any medical decisions. It should be noted that hearing aids/instruments cannot restore normal hearing and will not prevent or improve any hearing impairment. You are urged to use your hearing aid frequently to obtain full benefit from it.

When you Subscribe or purchase a hearing aid or accessories from us, you warrant that you are 18 years of age or older.

You acknowledge that Lexie hearing aids are medical devices and agree not to engage in the resale of the device(s), and to adhere to all relevant legislation and regulations concerning the use and disposal of such medical devices.

All information gathered through or supplied by this website, or any of the Providers, in any form, is deemed to be for informational purposes only and does not constitute medical or professional advice.

The information and Services supplied by us are not a substitute for a visit to a medical professional. Your use of this website does not create any professional relationship between us, and any privacy interests are limited to those contained in our Privacy Policy.

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